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Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed
Section *Novel Food and Toxicological Safety of the Food Chain*
28 February 2022

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SUMMARY REPORT

A.01 Feedback on discussions in recent meetings of the Working Group on Food Contact Materials.

The feedback concerned the Working Group meetings of 7-8 December 2021, and 7-8 February 2022. The Commission explained to the Member States that the main subject of both meetings had been the new Regulation on recycled plastic materials that is under preparation. During the meeting on 7 December the main principles of the new Regulation were explained, while during the second meeting the results of the consultations with the Member States and the public were discussed. During both meetings also a short update was given regarding the state of play on the ongoing projects related to Food Contact Materials (*16th amendment of the Regulation (EU) No 10/2011 and limits for metals in Ceramic materials and articles*). In addition exchanges took place with the Member States concerning enforcement matters observed by competent authorities, particularly concerning Beeswax on textile, Lignocellulose, the use of Bamboo in plastic, and risks from paper straws. During the meeting on 7 February, amendments to Annex I to Regulation (EU) No 10/2011 were discussed and in particular the setting of a limit on styrene in view of reported difficulties in migration testing, and the Commission's planned follow-up to resolve these ahead of laying down a limit.

A.02 Endorsement of a draft Commission Recommendation on the monitoring of the presence of glycoalkaloids in potatoes and potato-derived products (SANTE/10802/2021).

In the corresponding EFSA opinion certain exposure scenarios indicate a potential health concern in relation to the presence of glycoalkaloids in potatoes and potato products. However, there are still a lot of knowledge gaps as regards their occurrence and the factors involved, as well their presence in processed products. This recommendation aims to fill these gaps in view of possible future regulation aimed at ensuring a high level of human health protection. No comments were raised.

A.03 Exchange of views on perfluoroalkyl substances in food. Member States will be requested to communicate their position on:

- **a draft Commission Regulation amending Regulation (EC) No 1881/2006 as regards maximum levels of perfluoroalkyl substances in certain foodstuffs (SANTE/11183/2018)**
- **a draft Commission Recommendation on the monitoring of perfluoroalkyl substances in food (SANTE/10010/2021).**
- **a Commission Implementing Regulation laying down methods of sampling and analysis for the control of perfluoroalkyl substances in certain foodstuffs (SANTE/11354/2021)**

The Commission presented these drafts and explained their contents. The Commission explained some changes regarding maximum levels for certain fish species, made on the basis of additional data provided by a Member State. Several Member States expressed their support to the proposals. A Member State commented in favour of lower maximum levels for certain frequently consumed fish species, while another one requested more time to provide additional data in support of higher maximum levels for certain fish species. The Commission answered that the current maximum levels are proposed on the basis of sufficient data and taking into account the 'As Low As Reasonable Achievable' principle, and that the current levels aim to reconcile different positions from Member States. A Member State announced its intention to collect more data for fish and requested whether the maximum levels would be reviewed, taking into account new data. The Commission confirmed that this is indeed the intention. A Member State commented in favour of establishing only a maximum level for the sum of PFOS, PFOA, PFNA and PFHxS and not for the individual PFAS substances. The Commission explained that compliance with the sum maximum level is mainly driven by the PFOS concentration and that, in view of the health risks which are identified for PFAS, maximum levels for PFOS, PFOA, PFNA and PFHxS are appropriate to ensure a higher level of human health protection. A Member State commented against a maximum level for game meat, as it might impact on its production. The Commission explained that the maximum levels are set at the appropriate level on the basis of the occurrence data and that they will help to remove the products with the highest concentrations from the market. Taking into account data provided by that Member State, an exemption was made for bear meat. A Member State requested that all substances within the scope of the monitoring Recommendation would be included in the EFSA reporting format. The Commission will contact EFSA to arrange this. Some Member States commented against the establishment of indicative levels under the monitoring Recommendation, while others commented in favour of this. The Commission explained that these levels will trigger controls and investigations by Competent Authorities and Food Business Operators, which will help to consider the need for possible maximum levels at a later stage. The indicative levels are proposed on the basis of occurrence data and only a limited percentage of the products will exceed these levels. Furthermore, the investigations are recommended but not mandatory and it is clearly explained in the text that the indicative levels should not be used as a threshold to remove products from the market.

A.04 Mineral oil hydrocarbons in food: follow-up to the December 2021 Foodwatch report.

In December 2021, Foodwatch published a report on the presence of mineral oils in foods. In 19 products from different Member States, mineral oil aromatic hydrocarbons

(MOAH) were quantified. These findings were discussed with the Member States in a Working Group on contaminants on 10 December 2021. At that occasion Member States were asked to carry out controls on these products and, in case of positive findings, to carry out investigations towards the causes of the contamination. It was also stressed that, for products containing MOAH, awaiting the update of the EFSA risk assessment on MOHs in food (*by the end of 2022*), and because MOAH may contain genotoxic carcinogens, enforcement action should be taken on the basis or Art. 14 of Regulation (EC) No 178/2002.

In the meanwhile RASFF notifications have been issued for some of these products and it appears that the use of E905 (*microcrystalline wax, petroleum wax, synthetic paraffin*) in food contact materials might be related to the contamination of certain products. As the presence of MOAH in food is avoidable and as there are possible serious health risks, the Commission circulated through the RASFF a message requesting the relevant competent authorities to follow-up on the findings and to sample and analyse the products (*stock cubes and other products*) which have been found to contain MOAH and to perform investigations on the source of contamination (*ingredients, food additives, food contact materials, lubricants and others*) and to report on the outcome of the investigations. The Commission message included also the following statement: *"Given that MOAH are possible genotoxic carcinogens, in case of an indisputable quantified presence of MOAH (i.e. above the limit of quantification, determined in accordance with the JRC Guidance) confirmed by official control, these products should be withdrawn and recalled from the market, on the basis of Article 14 of the General Food Law (Regulation (EC) No 178/2002)".*

During the meeting, an exchange of views took place on the outcome of the investigations carried on by the Member States and on a possible further follow-up. Certain Member States reported on their follow-up actions, some indicated that they decide on the follow-up on a case-by-case basis, while several stressed the need for a harmonised approach at EU level. The Commission explained that, once the EFSA updated risk assessment will be available, discussions will start on the need for possible maximum levels for MOHs in food. In the meanwhile follow-up should be done in accordance with the approach summarised by the Commission, which was circulated via the RASFF. Some Member States requested to define harmonised limits of quantification (LOQs) for different food groups, in order to have the same cut-off values for enforcement throughout the EU. Performance requirements for LOQs in Table II of the JRC Guidance of maximum 0.5 mg/kg for dry foods with a low fat/oil content (< 4% fat/oil), 1 mg/kg for foods with a higher fat/oil content (> 4% fat/oil) and 2 mg/kg for fats/ oils should be considered for this. It was agreed to continue the discussions at a next meeting of the Standing Committee.

A.05 Feedback on discussions in recent meetings of the Working Groups on contaminants.

The Committee was informed:

- on the setting of maximum levels for dioxins and dioxin-like PCBs for foodstuffs not yet covered by EU legislation and for which in the meantime occurrence data have been made available in the EFSA database, such as meat and meat products from caprine animals, horse, rabbit, boar, game birds and venison and liver of caprine animals, horse and game birds and on the intension to extend the existing maximum level for hen eggs

to all poultry eggs, with the exception of goose eggs. In addition, taking into account the available occurrence data and the importance to ensure a high level of human health protection, in particular for vulnerable groups of the population, it is appropriate to lower already the maximum levels for dioxins and the sum of dioxins and dioxin-like PCBs in milk and dairy products.

The World Health Organisation (WHO) is currently performing a review of the WHO2005-TEF values, which is foreseen to be completed in 2023. Taking into account the conclusions of that scientific opinion, a comprehensive review of the maximum levels in feed and food is foreseen once WHO will have finalised its review and the updated TEF values are made available. The Committee was informed about the intention to submit these measures for an opinion at one of the next meetings;

- on the setting of maximum levels for T2 and HT2 toxins and the review of the existing maximum levels for deoxynivalenol. The technical discussions are still ongoing but in a final stage;

- that a stakeholder forum on 3-MCPD fatty acid esters took place on 23 February and one on acrylamide on 24 February 2022. The discussions on regulatory provisions will now continue in the working group;

- on the ongoing discussions related to the measures providing for the methods of sampling and analysis for the control of the levels of mycotoxins and plant toxins in food.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 1321/2013 as regards the name of the holder of the authorisation for the smoke flavouring primary product 'Scansmoke PB 1110.'

The Commission presented the draft Commission Implementing Regulation changing the authorisation holder for the smoke flavouring primary product 'Scansmoke PB 1110' as stated in Commission Implementing Regulation (EU) No 1321/2013 establishing the Union list of authorised smoke flavouring primary products. The applicant confirmed that no other changes or amendments to the authorisation were requested and in particular the smoke flavouring primary product Scansmoke PB 1110 and the production process remained unchanged. The proposed change is thus purely administrative in nature and therefore does not entail a new safety assessment. Implementing Regulation (EU) No 1321/2013 should be amended accordingly.

Vote taken by written procedure: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of glycolipids as a preservative in beverages.

The Commission presented the draft Commission Regulation authorising glycolipids as a new food additive for use in flavoured drinks, other non-alcoholic beverages and alcohol free beer and malt beverages. The proposed use was assessed by EFSA, which in June 2021 published its opinion establishing an acceptable daily intake (ADI) of 10 mg/kg bw per day and concluded that the exposure to glycolipids does not raise a safety concern for the uses and use levels proposed. Glycolipids, when used as a preservative

in beverages, prolong the shelf-life by protecting against deterioration caused by micro-organisms and growth of pathogenic micro-organisms. It is therefore appropriate to authorise the use of glycolipids as a preservative in beverages and to assign E 246 as E-number to this new food additive.

Vote taken by written procedure: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the presence of ethylene oxide in food additives.

This draft Commission Regulation was neither discussed nor tabled for a vote, as administrative procedures could not be completed on time. This will be done at a next meeting.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of Oat lecithin in Cocoa and Chocolate products as covered by Directive 2000/36/EC.

The Commission presented the draft Commission Regulation authorising oat lecithin as a new food additive for use in cocoa and chocolate products as covered by Directive 2000/36/EC. EFSA evaluated the safety of oat lecithin in 2018 and concluded that there is no safety concern for oat lecithin to be used as a food additive at the proposed use and use levels. Oat lecithin is a fractionated oat oil, which acts as an emulsifier and allows molten chocolate to be pumped easily during processing. Furthermore, oat lecithin prevents fat bloom, a greyish haze, from developing on the surface of products during storage. It is therefore appropriate to authorise the use of oat lecithin in cocoa and chocolate products and to assign E 322a as E-number to this new food additive.

Vote taken by written procedure: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Polyvinylpyrrolidone (E 1201) in food for special medical purposes in tablet and coated tablet forms.

The Commission presented the draft Commission Regulation authorising the use of polyvinylpyrrolidone (E1201) as a food additive in food for special medical purposes, in tablet and coated tablet forms. In July 2020 EFSA re-evaluated the safety of polyvinylpyrrolidone (E1201) as a food additive and concluded that the extension of use, at the proposed maximum permitted level and recommended consumption level, is not expected to be of a safety concern. During the production of the tablets for special medical purposes, polyvinylpyrrolidone strongly binds the ingredients, ensures their cohesion and slows down their disintegration. It is therefore appropriate to authorise the use of this additive as a stabiliser of food for special medical purposes in tablet and coated tablet forms.

Vote taken by written procedure: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of ascorbic acid and its salts (E 300-302) in Tuna.

This draft Commission Regulation was neither discussed nor tabled for vote, as administrative procedures could not be completed on time. This will be done at a next meeting.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food trans-resveratrol (from microbial source)

The Commission presented to the Committee the draft Commission Implementing Regulation authorising the removal of the maximum particle size requirement currently set out in the specifications of the novel food trans-resveratrol produced from a microbial source, so as to align them with the specifications of the chemically synthesized trans-resveratrol, which has no maximum particle size requirement. The measure is underpinned by an 2016 EFSA opinion on the chemically synthesised trans resveratrol. No comments were made.

Vote taken by written procedure: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2017/2470 authorising the placing on the market of mung bean (*Vigna radiata*) protein as a novel food under Regulation (EU) 2015/2283.

The Commission presented to the Committee the draft Commission Implementing Regulation (EU) authorising the placing on the market of mung bean (*Vigna radiata*) protein as a novel food. The measure, underpinned by an EFSA opinion, authorizes the use of mung bean (*Vigna radiata*) protein as protein products (e.g. egg replacer) in various type of foods. No comments were made.

Vote taken by written procedure: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use and the specifications of the novel food nicotinamide riboside chloride.

This draft Commission Implementing Regulation was neither discussed nor tabled for vote, as administrative procedures could not be completed on time. This will be done at a next meeting.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food galacto-oligosaccharide.

The Commission presented to the Committee the draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food galacto-oligosaccharide. The proposal concerns the

amendment of the conditions of use of the novel food galacto-oligosaccharide, in particular to extend its use to dairy confectionary, cheese and processed cheese, butter and spreads intended for the general population. One Member State commented that food supplements for infants and young children are viewed critically in the country.

Vote taken by written procedure: Favourable opinion.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) No 1881/2006 as regards maximum levels of delta-9-tetrahydrocannabinol (Δ9-THC) in hemp seeds and products derived therefrom.

The draft Regulation establishes maximum levels for delta-9-tetrahydrocannabinol (Δ9-THC) in hemp seeds and products derived therefrom to ensure a high level of human health protection. Following requests made at the Working Group to regulate also Δ8-THC, the Commission informed the Committee of its intention to address a request to EFSA for a risk assessment on Δ8-THC. The Committee was also informed of the comments received from Dava Foods (Denmark), Finola Oy (Finland), Trans Farm Oy (Finland) and from two scientists as regards regulations in other constituencies in the world, and providing comments on the EFSA opinion. Following comments by Member States received in advance of the meeting, some changes were introduced and the date of application of the regulation was set to 1st January 2023.It was also clarified that products placed on the market after the date of application will have to comply with the maximum level, e.g. hempseeds placed on the market in retail packages after 1st January 2023 will have to comply with the maximum level. No further comments were raised

Vote taken by written procedure: Favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) No 1881/2006 as regards maximum levels of ochratoxin A in certain foodstuffs.

EFSA concluded in its scientific opinion that the presence of ochratoxin A (OTA) in food indicates a possible health concern for certain consumer groups. In order to ensure a high level of human health protection, the draft Regulation establishes maximum levels for ochratoxin A in certain foods such as dried fruit other than dried vine fruit, certain liquorice products, dried herbs, certain ingredients for herbal infusions, certain oilseeds, pistachio nuts, and cocoa powder and the existing maximum level for certain spices is extended to all spices. The existing maximum level for ochratoxin A is lowered in bakery products, dried vine fruit, roasted coffee and soluble coffee. Even if the relationship between the levels of ochratoxin A in malt and in non-alcoholic malt beverages, and in dried dates and date syrup needs to be further clarified, a maximum level is set in non-alcoholic malt beverages and date syrup. The maximum level in non-alcoholic beverages and in date syrup is to be reviewed within two years, based on more monitoring data and clarification on the relationship of the level of OTA in malt used as ingredient and the level of OTA in malt beverage, and the level of OTA in dried dates used as raw material and the level of OTA in dried dates. For cheese and ham, additional monitoring on the presence of ochratoxin A is appropriate before establishing maximum levels. Following comments received in advance of the meeting, a higher maximum level was agreed for bakery wares, cereal snacks and breakfast cereals containing at least 20 % dried vine fruit and/or dried figs. The Committee was also

informed of the comments received from the Asociación Española del Café (Spanish Coffee Association). No further comments were raised.

Vote taken by written procedure: Favourable opinion.

B.13 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) No 1881/2006 as regards maximum levels of hydrocyanic acid in certain foodstuffs.

The draft Regulation establishes maximum levels for hydrocyanic acid in linseed, almonds, cassava, root and cassava flour to ensure a high level of human health protection. No comments were raised.

Vote taken by written procedure: Favourable opinion.

B.14 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) correcting the French language version of Implementing Regulation (EU) 2021/1533 imposing special conditions governing the import of feed and food originating in or dispatched from Japan following the accident at the Fukushima nuclear power station.

The draft Regulation relates to a translation error in the French language version of Commission Implementing Regulation (EU) 2021/1533. As the error is substantial, the correction is to be done by correcting act and not by corrigendum.

Vote taken by written procedure: Favourable opinion.

B.15 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Regulation (EC) No 333/2007 as regards the sampling requirements for fish and terrestrial animals..

The Commission presented the draft Commission Implementing Regulation and explained its contents. No Member State made further comments.

Vote taken by written procedure: Favourable opinion.

C.01 Exchange of views of the Committee on a draft Commission Regulation (EU) on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008.

The Commission presented the state of play regarding the draft text discussed under this point. It explained the changes it made to the text as a consequence of the consultation with the Member States and the public on the draft text published on 8 December for public feedback, the relation between the recycling text and Regulation (EU) No 10/2011 and further explained recycling schemes. The Commission also presented the changes it made to chapter IV of the draft Regulation in view of comments by Member States. Further discussion took place concerning the apparent magnitude of the use of plastic behind a functional barrier. Following a clarification of the scope, this recycling technology will become fully subject to the new Regulation and a potential transitional provision to address possible consequences forthcoming from this clarification was therefore discussed. The Commission clarified a number of matters following questions from Member States: some of them stated that they would need some further time to study the text, and asked the Commission to ensure a high level of safety with respect to the placing onto the market of recycled plastic materials and articles in accordance with chapter IV. Here the Commission services sought to re-

assure Member States by pointing out to the safeguards the Regulation would introduce, but would also consider introducing further wording regarding the obligations of operators on the safety of those materials. Also the use of recycled plastic behind a functional barrier was discussed in this context. A discussion also took place regarding the alignment of this Recycling text with the waste legislation. The Commission explained to the Member States that, to enable enforcement, the Regulation has to introduce requirements on the quality of plastic input originating from collection; however, the developments under the revision of the Waste Framework Directive will be followed. Where those developments lead to a level of quality that would be at least comparable to that which is required under the draft Regulation in the future, it would be amended to refer to the Waste Regulation.